



ENVIRONMENTAL PROTECTION AGENCY

6560-50-P

[EPA-HQ-OPPT-2013-0275; FRL-9529-9]

**Information Collection Request Submitted to OMB for Review and Approval; Comment Request; ICR Addendum for the Second List of Chemicals; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA has submitted the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*): “ICR Addendum for the Second List of Chemicals; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP)” (EPA ICR No. 2488.01, OMB Control No. 2070-[new]). This is a new ICR that will amend an ICR that is currently approved under OMB Control No. 2070-0176 (EPA ICR No. 2249) and that covers the first list of chemicals. The ICR, which is abstracted below, describes the nature of the information collection activity and its expected burden and costs.

**DATES:** Submit comments on or before [insert date 30 days after publication in the *Federal Register*].

**ADDRESSES:** Submit your comments, referencing Docket ID Number EPA-HQ-OPPT-2013-0275, to (1) EPA online using <http://www.regulations.gov> (our preferred method) or by mail to: Pollution Prevention and Toxics Docket, Environmental Protection Agency Docket Center (28221T), 1200 Pennsylvania Ave., NW, Washington, DC 20460, and (2) OMB via email to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov) (address your comments to the OMB Desk Officer for EPA).

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity,

threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

**FOR FURTHER INFORMATION CONTACT:** Pat West, (7203M), Office of Science Coordination and Policy (OSCP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-1656; fax number: (202) 564-8482; e-mail address: [west.pat@epa.gov](mailto:west.pat@epa.gov).

**SUPPLEMENTARY INFORMATION:** Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at [www.regulations.gov](http://www.regulations.gov) or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

EPA received several comments in response to its solicitation of comments pursuant to 5 CFR 1320.8(d) in the *Federal Register* issue of November 17, 2010 (75 FR 70569). The ICR submitted to OMB includes EPA's responses, and reflects revisions made in response to those comments. Please note that when comments were sought in 2010, the draft ICR was identified under EPA ICR No. 2249.02 and OMB Control No. 2070-0176, and comments were directed to Docket ID No. EPA-HQ-OPPT-2007-1081, which had been established for the initial ICR related to List 1 chemicals. Given the resulting confusion in finding documents in that docket, EPA has established a new docket, which is linked to the old docket.

**ICR Status:** This is an addendum to an existing ICR that is currently approved under OMB Control No. 2070-0176 (EPA ICR No. 2249), covering the first list of chemicals screened under the EDSP. Under OMB regulations, the Agency may continue to conduct or sponsor an approved

collection of information while this submission is pending at OMB. In this case, this applies to the activities associated with the chemicals on List 1, but not those associated with the chemicals on List 2. Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

**Abstract:** This ICR covers the information collection activities associated with Tier 1 screening of the List 2 Chemicals under EPA's EDSP. List 2 consists of 109 identified chemicals, 41 of which are pesticide active ingredients (PAIs) and 68 are chemicals identified under the Safe Drinking Water Act (SDWA). The EDSP is established under section 408(p) of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 346a(p)), which requires EPA to develop a chemical screening program using appropriate validated test systems and other scientifically relevant information to determine whether certain substances may have hormonal effects. The EDSP consists of a two-tiered approach to screen chemicals for potential endocrine disrupting effects. The purpose of Tier 1 screening is to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems using a battery of assays. Substances that have the potential to interact with estrogen, androgen or thyroid systems may proceed to Tier 2, which is designed to identify any adverse endocrine-related effects caused by the substance, and establish a quantitative relationship between the dose and that endocrine effect. Additional information about the EDSP is available at <http://www.epa.gov/endo>.

This ICR addendum covers the information collection activities and burden associated with issuing orders, generating and collecting data for List 2 Chemicals. The information collection activities otherwise remain the same as those described in the existing ICR that covers EDSP Tier 1 screening of List 1 Chemicals, with a few modifications that are necessary to address procedural differences that apply to SDWA chemicals. The Agency is also establishing

an electronic mechanism for these activities to reduce burden and increase efficiencies.

**Form Numbers:** EPA form numbers 6300-05; 6300-05-C; 6300-06; and 6300-06-C.

**Respondents/Affected Entities:** Entities potentially affected by this ICR are those who receive an EDSP test order issued by the Agency because they are a registrant or manufacturer/importer of a chemical substance identified on List 2. Under FFDCA section 408(p)(5)(A), EPA “shall issue” EDSP test orders “to a registrant of a substance for which testing is required . . . or to a person who manufactures or imports a substance for which testing is required.”

**Respondent’s Obligation to Respond:** Mandatory under FFDCA section 408(p).

**Estimated Number of Respondents:** 1,000.

**Frequency of Response:** On occasion.

**Estimated Burden:** The per response burden is estimated to range between 204 and 4,729 hours, depending on the respondent category and activities. The total annualized burden is estimated to be 296,820 hours. Burden is defined at 5 CFR 1320.03(b).

**Estimated Cost:** The per response cost is estimated to range between \$18,842 and \$297,171, depending on the respondent category and activities. The total annualized cost is estimated to be \$21,054,546. This includes \$400 for non-labor costs related to mailing the submissions. Delivery of paper submissions will be eliminated with the full implementation of the electronic system.

**Changes in Burden Estimates:** This represents an increase of 296,820 hours in the total estimated annualized burden compared with that currently approved by OMB. This is a program change that reflects the planned issuance of Tier 1 orders for List 2 chemicals to be screened under Tier 1 of the EDSP.

Dated: June 4, 2013

John Moses, Director, Collection Strategies Division

